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| 42074 | 7590 | 06/03/2008 | EXAMINER | |
| FAEGRE & BENSON, LLP | | | RAPILLO, KRISTINE K | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionBSC@faegre.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/789,636 | ROSSINNI ET AL. | |
| | Examiner | Art Unit | |
| | KRISTINE K. RAPILLO | 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1- 14 and 16 - 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 and 16 - 27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 February 2008 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/19/2004; 11/9/2005; 2/8/2008</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 1 – 14 and 16 - 27 are pending.

Notice to Applicant

1. This communication is in response to the amendment filed 3/21/2008. Claims 16 and 17 are amended. Claim 27 is new. Claim 15 is cancelled. Claims 1 – 14 and 16 – 27 are presented for examination.

Drawings

1. The objection to the drawings is hereby withdrawn based on the amendment filed 3/21/2008.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 8, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims 8, 9, and 10 are directed toward a method, whereas the independent claim upon which they dependent is directed to an apparatus, and are therefore considered to be indefinite under 35 U.S.C. 112, second paragraph - see *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990). For example, claim 9 contains the following indefinite language: "the method of claim 1". However, claim 1 is directed toward a system or apparatus.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5. Claims 8, 9, and 10 are rejected under 35 U.S.C. 101 because the claim is directed to neither a "process" nor a "machine," but rather overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only, (see *Id.* at 1551). For example, claim 9 contains the following indefinite language: "the method of claim 1". However, claim 1 is directed toward a system or apparatus.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

In regard to claim 1 (Original), Snell teaches a system for delivering and gathering medical information, the system comprising:

- a medical data set, wherein the medical data set includes at least a first data set derived from a first implantable medical device of a first implantable medical device type (column 3, lines 5 - 9);

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- a server, wherein the server includes a processor (column 6, lines 32 – 60) and a computer readable medium (column 9, lines 2 – 20 and claim 10), and wherein the computer readable medium includes instructions executable by the microprocessor to:
 - identify a portion of the medical data set under review (column 8, lines 1 – 43);
 - receive an analysis of the portion of the medical data set under review from the at least one member of the review group (column 9, lines 21 – 47).

Snell fails to teach a system for delivering and gathering information, the system comprising: a second data set derived from a second implantable medical device from a second implantable medical device type.

Norris teaches a system comprising

- a second data set derived from a second implantable medical device from a second implantable medical device type (Figure 1 and column 7, lines 34 – 38). Figure 1 in Norris shows an illustration of an IMD implanted into a patient's chest with a communication network to demonstrate the transfer of data from the device to a computer system;
- identify a review group associated with the portion of the medical data set under review, wherein the review group includes at least one member (column 5, lines 37 – 50); and,
- provide the portion of the medical data set under review to at least one member of the review group (column 5, lines 37 – 50).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system comprising a second data set derived from a second implantable medical device from a second implantable medical device type as taught by Norris, within the system of Snell, with the motivation of providing a system which communicates data to a medical information network which is able to deliver clinical tools to a caregiver to assist in improved patient care (Norris: column 5, lines 8 – 17).

In regard to claim 2, (Original), Snell teaches the system of claim 1. Snell fails to teach a system wherein the medical data set further includes at least one of a first physician provided objective data and

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a first physician provided subjective data associated with the first data set, and at least one of a second physician provided objective data and a second physician provided subjective data associated with the second data set.

Norris teaches a system wherein the medical data set further includes at least one of a first physician provided objective data and a first physician provided subjective data associated with the first data set, and at least one of a second physician provided objective data and a second physician provided subjective data associated with the second data set (column 11, lines 25 – 45). Norris describes a system in which both objective and subjective data is gathered and input into a database to allow amore thorough analysis and diagnosis.

The motivation to combine the teachings of Norris and Snell is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 3 (Original) Snell teaches the system of claim 1. Snell fails to teach a system wherein the analysis is a medical diagnosis, and wherein the at least one member of the review group is selected from a group consisting of: a specialist versed in providing the medical diagnosis based at least in part on the portion of the medical data set under review, and a physician versed in providing the medical diagnosis based at least in part on the portion of the medical data set under review.

Norris teaches a system wherein the analysis is a medical diagnosis, and wherein the at least one member of the review group is selected from a group consisting of: a specialist versed in providing the medical diagnosis based at least in part on the portion of the medical data set under review (column 11, lines 34 – 45), and a physician versed in providing the medical diagnosis based at least in part on the portion of the medical data set under review (column 11, lines 34 – 45).

The motivation to combine the teachings of Norris and Snell is discussed in the rejection of claim 1, and incorporated herein.

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In regard to claim 4 (Original), Snell teaches the system of claim 1, wherein the computer readable medium includes instructions executable by the microprocessor (Snell: column 9, lines 2 – 20 and claim 10) to:

Snell fails to teach a system wherein the computer readable medium includes instructions to receive a third data set derived from a third implantable medical device; compare at least a portion of the third data set with a corresponding portion of the first data set and a corresponding portion of the second data set, wherein it is determined that the first data set and the third data set are similar; and communicate the medical diagnosis associated with the first data set to a provider of the third data set.

Norris teaches a system wherein the computer readable medium includes instructions to receive a third data set derived from a third implantable medical device (Norris: Figure 1 and column 7, lines 34 – 38); compare at least a portion of the third data set with a corresponding portion of the first data set and a corresponding portion of the second data set, wherein it is determined that the first data set and the third data set are similar (Norris: column 16, lines 7 – 28); and communicate the medical diagnosis associated with the first data set to a provider of the third data set (Norris: column 5, lines 37 – 50). Norris discloses providing data to a centralized database which would allow all pertinent providers access to the data and diagnosis of other providers (i.e. specialists).

The motivation to combine the teachings of Norris and Snell is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 5 (Original) Snell teaches the system of claim 4. Snell fails to teach a system wherein the provider of the third data set is selected from a group consisting of: a patient associated with the third implantable medical device, and a physician overseeing a patient associated with the third implantable medical device.

Norris teaches a system wherein the provider of the third data set is selected from a group consisting of: a patient associated with the third implantable medical device (Figure 1 and column 7, lines 34 – 38), and a physician overseeing a patient associated with the third implantable medical device (Norris: column 5, lines 8 – 13).

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The motivation to combine Snell and Norris is discussed in the rejection of claim 1 and is incorporated herein.

In regard to claim 6 (Original) Snell teaches the systems of claim 1. Snell fails to teach a system wherein the first data set is converted to provide a first graphical representation, and wherein the second data set is converted to provide a second graphical representation.

Norris teaches a system wherein the first data set is converted to provide a first graphical representation, and wherein the second data set is converted to provide a second graphical representation (Norris: column 11, lines 4 – 11).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a system wherein the first data set is converted to provide a first graphical representation as taught by Norris, within the system of Snell, with the motivation of enabling a health care provider the means to review data in a more efficient manner (column 10, line 67 through column 11, line 3).

In regard to claim 7 (Original) Snell teaches the system of claim 6. Snell fails to teach a system wherein the computer readable medium includes instructions executable by the microprocessor to: distribute an access tool to each member of the review group, wherein the access tool is operable to display the first graphical representation and the second graphical representation.

Norris teaches a system wherein the computer readable medium includes instructions executable by the microprocessor to: distribute an access tool to each member of the review group, wherein the access tool is operable to display the first graphical representation and the second graphical representation (Norris: column 8, lines 50 – 56).

The motivation to combine Snell and Norris is discussed in the rejection of claim 6 and is incorporated herein.

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In regard to claim 11 (Original), Snell teaches a method for obtaining medical information feedback, the method comprising: receiving a data set originating from an implantable medical device (column 6, lines 12 – 22).

Snell fails to teach a method for identifying a review group associated with data set, wherein the review group includes one or more members, communicating the data set to at least one member of the review group, receiving an analysis of the data set from the at least one member of the review group, and associating the analysis with the data set.

Norris teaches a method for identifying a review group associated with data set, wherein the review group includes one or more members (column 8, lines 1 – 43), communicating the data set to at least one member of the review group (Norris: column 13, line 56 through column 14, line 2 and column 14, lines 16 – 20), receiving an analysis of the data set from the at least one member of the review group Norris: Figure 4 and column 14, lines 16 – 34), and associating the analysis with the data set (Norris: column 14, lines 35 – 41).

The motivation to combine Snell and Norris is discussed in the rejection of claim 1 and is incorporated herein.

In regard to claim 12 (Original), Snell teaches the method of claim 11, wherein the analysis is a medical diagnosis (Snell: column 7, lines 12 – 27).

Snell fails to teach a method wherein the at least one member of the review group is a specialist versed in providing the medical diagnosis based at least in part on the data set.

Norris teaches a method wherein the at least one member of the review group is a specialist versed in providing the medical diagnosis based at least in part on the data set (Norris: column 11, lines 25 – 45).

The motivation to combine Snell and Norris is discussed in the rejection of claim 1 and is incorporated herein.

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In regard to claim 13 (Original), Snell teaches the method of claim 12, wherein the data set is a first data set, wherein the implantable medical device is a first implantable medical device (Snell: column 3, lines 5 – 9). Snell fails to teach a method wherein the method further comprises: receiving a second data set originating from a second implantable medical device; comparing the second data set with the first data set wherein it is determined that the first data set and the second data set are similar; and communicating the medical diagnosis associated with the first data set to a provider of the second data set.

Norris teaches a method wherein the method further comprises: receiving a second data set originating from a second implantable medical device (Norris: Figure 1 and column 7, lines 34 - 38); comparing the second data set with the first data set wherein it is determined that the first data set and the second data set are similar (Norris: column 16, lines 7 – 28); and communicating the medical diagnosis associated with the first data set to a provider of the second data set (Norris: column 5, lines 37 - 50).

The motivation to combine Snell and Norris is discussed in the rejection of claim 1 and is incorporated herein.

In regard to claim 14 (Original) Snell teaches the method of claim 13. Snell fails to teach a method wherein the provider of the second data set is selected from a group consisting of: a patient associated with the second implantable medical device, and a physician overseeing a patient associated with the second implantable medical device.

Norris teaches a method wherein the provider of the second data set is selected from a group consisting of: a patient associated with the second implantable medical device (Norris: Figure 1 and column 7, lines 34 – 38), and a physician overseeing a patient associated with the second implantable medical device (Norris: column 5, lines 8 – 13).

The motivation to combine Snell and Norris is discussed in the rejection of claim 1, and is incorporated herein.

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In regard to claim 16 (Currently Amended) Snell teaches the method of claim 27. Snell fails to teach the method further comprising: distributing an access tool to each member of the review group, wherein the access tool is operable to display the first graphical representation and the second graphical representation.

Norris teaches a method further comprising: distributing an access tool to each member of the review group, wherein the access tool is operable to display the first graphical representation and the second graphical representation (Norris: column 8, lines 50 – 56).

The motivation to combine Snell and Norris is discussed in the rejection of claim 6, and is incorporated herein.

In regard to claim 17 (Currently Amended) Snell teaches the method of claim 27. Snell fails to teach a method, the first graphical representation is an electrocardiogram.

Norris teaches a method, the first graphical representation is an electrocardiogram (Norris: column 11, lines 4 – 8).

The motivation to combine Snell and Norris is discussed in the rejection of claim 6 and is incorporated herein.

In regard to claim 18 (Original) Snell teaches the method of claim 11. Snell fails to teach a method wherein the data set is stripped of identification information prior to communicating the data set to the at least one member of the review group.

Norris teaches a method wherein the data set is stripped of identification information prior to communicating the data set to the at least one member of the review group (column 5, lines 40 – 42). As is old and well known, government and international database repositories are stripped of patient identifying information when used to educate the public.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a method wherein the data set is stripped of identification information prior to communicating the data set to the at least one member of the review group as taught by Norris, within the

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method of Snell, with the motivation of providing a tool to aid health care providers in medical diagnosis (column 12, lines 47 – 57).

In regard to claim 19 (Original), Snell teaches the method of claim 11, wherein the data set is received from a source selected from a group consisting of: a programmer (Snell: column 2, lines 38 – 56), a bedside monitor (Snell: column 5, lines 44 – 53), and a mobile monitor (Snell: column 8, lines 44 – 53). Snell fails to teach a method wherein the data is received from a bedside monitor.

In regard to claim 20 (Original) Snell teaches the method of claim 11. Snell fails to teach a method wherein the review group includes at least a first specialist and a second specialist, wherein the first and second specialists are versed in providing medical diagnosis based at least in part on information included within the data set, and wherein the analysis includes a first medical diagnosis from the first specialist and a second diagnosis from the second specialist.

Norris teaches a method wherein the review group includes at least a first specialist and a second specialist, wherein the first and second specialists are versed in providing medical diagnosis based at least in part on information included within the data set, and wherein the analysis includes a first medical diagnosis from the first specialist and a second diagnosis from the second specialist (Norris: column 11, lines 225 – 45 and column 15, lines 15 – 29).

The motivation to combine Snell and Norris is discussed in the rejection of claim 1 and is incorporated herein.

In regard to claim 21 (Original) Snell teaches the method of claim 20. Snell fails to teach a method wherein the data set is a first data set, wherein the implantable medical device is a first implantable medical device, and wherein the method further comprises: receiving a second data set originating from a second implantable medical device; comparing the second data set with the first data set wherein it is determined that the first data set and the second data set are similar; and communicating the first medical diagnosis and the second medical diagnosis to a provider of the second data set.

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Norris teaches a method wherein the data set is a first data set, wherein the implantable medical device is a first implantable medical device, and wherein the method further comprises: receiving a second data set originating from a second implantable medical device (Norris: Figure 1 and column 7, lines 34 – 38); comparing the second data set with the first data set wherein it is determined that the first data set and the second data set are similar (Norris: column 16, lines 7 -28); and communicating the first medical diagnosis and the second medical diagnosis to a provider of the second data set (Norris: column 5, lines 37 – 50).

The motivation to combine the teachings of Snell and Norris is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 22 (Original) Snell teaches the method of claim 11. Snell fails to teach a method further comprising: augmenting the data set to create an augmented data set, wherein the augmented data set includes at least one of a physician provided objective data and a physician provided subjective data.

Norris teaches a method further comprising: augmenting the data set to create an augmented data set, wherein the augmented data set includes at least one of a physician provided objective data and a physician provided subjective data (column 11, lines 25 – 45).

The motivation to combine the teachings of Snell and Norris is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 23 (Original) Snell teaches the method of claim 22. Snell fails to teach a method wherein the analysis is a medical diagnosis based at least in part on the augmented data set.

Norris teaches a method wherein the analysis is a medical diagnosis based at least in part on the augmented data set (column 11, lines 25 – 45).

The motivation to combine the teachings of Snell and Norris is discussed in the rejection of claim 1, and incorporated herein.

In regard to claim 24 (Original), Snell teaches a system for distributing medical data, the system comprising:

- a medical data database, wherein the medical data database includes a first data set originated from an implantable medical device (Snell: column 3, lines 5 - 9). Snell fails to teach a second data set originated from the implantable medical device;
- a server, wherein the server includes a processor (Snell: column 6, lines 32 – 60) and a computer readable medium (Snell: column 9, lines 2 – 20 and claim 10), and wherein the computer readable medium includes instructions executable by the processor to: receive a request for medical data, wherein the request includes an indication of the implantable medical device; access the first data set and the second data set from the medical data database; and communicate the first data set and the second data set to a recipient across a communication network;
- receive a request for medical data, wherein the request includes an indication of the implantable medical device (column 14, lines 19 – 35); and,
- access the first data set and the second data set from the medical data database (column 4, lines 19 – 35).

Snell fails to teach a system wherein the computer readable medium includes instructions executable by the processor to: receive a request for medical data, wherein the request includes an indication of the implantable medical device; access the first data set and the second data set from the medical data database; and communicate the first data set and the second data set to a recipient across a communication network.

Norris teaches a system wherein the computer readable medium includes instructions executable by the processor to: communicate the first data set and the second data set to a recipient across a communication network (Norris: column 5, lines 37 - 50).

The motivation to combine the teachings of Snell and Norris is discussed in the rejection of claim 1, and incorporated herein.

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In regard to claim 25 (Original), Snell teaches the system of claim 24, wherein the implantable medical device is implanted in a patient, and wherein the recipient is a physician of the patient (column 14, lines 19 – 35).

In regard to claim 26 (Original) Snell teaches the system of claim 24. Snell fails to teach a system wherein the first data set is converted to provide a first graphical representation, and wherein the second data set is converted to provide a second graphical representation.

Norris teaches a system wherein the first data set is converted to provide a first graphical representation, and wherein the second data set is converted to provide a second graphical representation (Norris: column 11, lines 4 – 11).

The motivation to combine the teachings of Snell and Norris is discussed in the rejection of claim 6, and incorporated herein.

In regard to claim 27 (New) Snell teaches the method of claim 11. Snell fails to teach a method wherein the first data set is converted to provide a first graphical representation, and wherein the second data set is converted to provide a second graphical representation.

Norris teaches a method wherein the first data set is converted to provide a first graphical representation, and wherein the second data set is converted to provide a second graphical representation (Norris: column 11, lines 4 – 11).

The motivation to combine the teachings of Snell and Norris is discussed in the rejection of claim 6, and incorporated herein.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTINE K. RAPILLO whose telephone number is (571)270-3325. The examiner can normally be reached on Monday to Thursday 6:30 am to 4 pm Eastern Time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KKR

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626